

INVENTION REPORT

1. (a) Title of discovery.

Autosynchronous Balloon Pumping System for Temporary Cardiac Assistance

(b) Grant number under which it was developed.

HE-06510

2. Full name of inventor and all persons directly contributing to the invention.

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3. Name and address of facility at which discovery was made.

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4. Contribution of the facility to the discovery in men, money, or materials.

Dr. Kantrowitz's salary is drawn from institutional funds.

5. Patent policy of the facility.

Article 7 of the By-laws of Maimonides Medical Center states the following patent policies:

"All inventions, discoveries, and improvements made by any person in the employ of the Corporation or while receiving any compensation for his services or while using any of the facilities of the Hospital, shall be the property of the Corporation to be used by it for the purposes of furthering the medical sciences."

"The Board of Trustees may, however, permit the discoverer or the inventor to participate in the income, if any, from the discovery of the invention. The provisions of this Article may be waived by the Board of Trustees."

6. Name and address of any other organization(s) contributing to discovery.

None

7. Contribution of the organization(s) in men, money, facilities, or materials.

Not applicable

8. Patent policies of these organizations.

Not applicable

9. Detailed description of invention.

The intraarterial cardiac assisting device (IACA), developed in this laboratory, represents a modification of the attempts of earlier investigators to devise a means for quickly combating profound cardiogenic shock. Clauss et al. in 1961 and Soroff in 1963 tried to provide circulatory assistance to the heart by means of a bellows pump aspirating blood through a cannula in a major artery. Mouloupoulos et al. in 1962 used an intraarterial latex rubber balloon as a device for diastolic augmentation. Clauss has also (1964) experimented with intraarterial balloon pumping. The device described here differs from previous ones in several aspects: a polyurethane balloon is used rather than one of latex; the gas used to inflate the balloon is helium rather than CO₂; the balloon contains a built-in pressure transducer; and a braid of thin copper wire in the balloon allows it to adapt to the shape of the aorta.

The IACA consists of an extracorporeal and an intracorporeal unit connected during use. The extracorporeal unit is an electronically controlled solenoid valve. The intracorporeal unit (Figure 1), comprised of a flexible polyurethane chamber with a Teflon catheter attached to one end, can be sterilized. The chamber, fabricated in our laboratories, is made by coating a glass mold with a 10-15% polyurethane tetrahydrofuran solution. The resulting membrane is only 0.100-0.125 mm thick, but the material is so tough that it can withstand pressure of 250 mm Hg without undergoing elastic deformation, and a considerably higher pressure before bursting. This allows a wide margin of safety during actual use. The chamber is 10-17 cm long and 1-2 cm in diameter, depending upon the size of the aorta for which it is intended and the pumping volume required. It tapers at each end to a cylindrical sleeve about 1 cm long and 0.5 cm in diameter. A section of woven, flexible copper tubing (electrical shielding), approximately 3-5 mm in diameter, is introduced into the chamber, spanning its length. A pressure transducer of the semiconductor strain-gage type is tightly fitted into the end of the catheter proximal to the heart. Thus positioned, the strain-gage is insensitive to pressure changes within the chamber but records blood pressure changes at the site where the chamber is positioned. The catheter, which is slipped over the end of the chamber distal to the heart, consists of two concentric, heat-shrinkable Teflon tubes; it is 60-70 cm long

and 5 mm in outside diameter. The catheter connects the intraarterial chamber and the extracorporeal unit, and leads from the pressure sensor are carried between the two tubes. All junctions are made helium-tight: the intracorporeal ones with polyurethane and the extracorporeal ones with epoxy.

For catheterization, the intracorporeal unit is stiffened by the insertion of a long catheter guide which reaches to the tip of the chamber. After the chamber is in place, the guide is withdrawn and the woven copper tube allows the chamber to regain its flexibility. When in operation, the assembled unit is driven by helium which is admitted into the chamber through the meshed copper tubing of the catheter. Helium is used because its low density assures rapid passage through the narrow catheter.

By means of a modified dual-beam oscilloscope, a preselected point either of the central aortic pressure, as obtained from the transducer, or of the ECG controls the solenoid valve of the pumping unit. Phase and duration of the inflation cycle can be adjusted independently of each other.

10. Objectives, advantages, and uses of the discovery.

The intraarterial cardiac assisting device was developed for the ultimate purpose of providing a practical method of rapid, effective assistance to the patient in profound, refractory cardiogenic shock. Some important advantages of the IACA are:

a) Since the pumping occurs in the upper thoracic aorta, the difficulties associated with other counterpulsation methods are overcome. In patients who require cardiac assistance, the peripheral arteries are usually sclerotic; this imposes a restriction on the size of the catheter that can be introduced, and therefore, on the stroke volume. Effectiveness of these units is thus limited.

b) Only polyurethane and Teflon are in contact with the blood; both of these materials are biologically compatible.

c) Because the driving gas, helium, has a low density, a small-diameter catheter can be used.

d) Correct timing of the pumping is critical to effectiveness of the system. In the absence of useable ECG signals, the option to achieve synchronization by using pressures measured in the aorta by the strain-gage is important.

e) The copper braid inside the balloon allows the pumping chamber to adapt to the shape of the aorta, reducing trauma to the intima. It can be stretched during insertion to minimize its diameter and also that of the balloon.

f) Since the position of the device can be determined from the pulse shapes measured at the tip, fluoroscopy is not required for insertion, simplifying the procedure.

g) With the IACA there is no high-velocity blood flow through a catheter, and thus, damage to blood elements is reduced.

11. Your opinion of the importance and usefulness of the discovery:

- (a) In the United States.
- (b) In foreign countries.

Fourteen of every 100 patients with acute myocardial infarction suffer profound cardiogenic shock. Of these patients 9-13 are unresponsive to medical therapy and need circulatory assistance.

In cardiac arrest cases, a combination of IACA and existing external massage apparatus may be effective. For further explanation of the usefulness of this device, see Item 10.

12. Personal desire on applying for a patent on the discovery.

Development in the public interest.

13. Why publication would not be adequate to insure the availability of the discovery to the public. Has a full description ever been published or submitted for publication?

A report has been presented at the Chicago meeting of the American Society for Artificial Internal Organs on April 16, 1967. Publication of the report (manuscript enclosed) will be in June 1967. Abstracts of this report were sent to the program committee of several professional groups during February 1967.

14. Brief statement on how the invention was conceived, its reduction to actual practice, and the dates of these events. Is invention in public use? If so, since what date has it been in public use?

The invention is a variation of the balloon pumping method for increasing blood circulation. The modifications described in Item 9 were first conceived by Adrian Kantrowitz and associates. In April 1966, the need for an improved device was discussed at a staff meeting of the Surgical Research Laboratory of the Department of Surgery, Maimonides Medical Center. The device was constructed and the first experiments were begun in May 1966. A total of 50 experiments has been performed on 44 unselected mongrel dogs and 2 calves, using both normal animals and those with experimentally induced shock.

15. Brief statement concerning supporting evidence which you have at hand which may be used as proof of Item 14--for instance, laboratory notebooks, letters, and the like.

Experimental data are in the laboratory. They have been presented at a meeting of the A.S.A.I.O. in April 1967 and will be published in the Transactions of that society in June 1967. A sample of the experimental results obtained since April 1967 by Dr. Steinar Tjonneland are shown in Figure 2.

16. Brief statement on disclosure of the discovery to others.

First disclosure beyond the laboratory staff was to the A.S.A.I.O. in April 1967. (See Item 15)

17. Dates, current location, and names of persons present during development of experimental data.

Dr. Wladimir Schilt and Mr. Paul Freed carried out experiments under the direction of Dr. Adrian Kantrowitz. Members of the research staff who were present during development of the experimental data include Drs. Ghassan A. Khalil, Sandra Samuels, Hans E. Carstensen, Toru Okura, and Steinar Tjonneland--all of whom are now at the Surgical Research Laboratory, Maimonides Medical Center.

18. Information as to the state of the art, publication, public use being made of the art at the time of discovery.

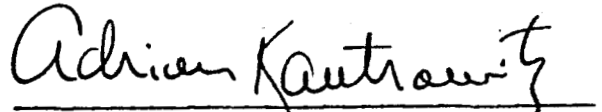
Circulatory assistance to the failing heart through reduction of systolic and elevation of diastolic pressures has been attempted by diastolic augmentation and synchronous counterpulsation. Kantrowitz and McKinnon (1959),¹ were among the early investigators to explore diastolic augmentation for permanent circulatory support. Clauss et al. (1961),² and Soroff et al. (1963)³ used a bellows pump which aspirates blood through a cannula in a major artery during systole, thus lowering the systolic pressure, and returns the blood during diastole, elevating the diastolic perfusion pressure. This procedure, carried out experimentally (in dogs) and clinically, has apparently given variable results. An intraarterial latex rubber balloon used as a diastolic pumping device was employed by Mouloupoulos⁴ who performed experiments only on normal dogs, using a closed system and CO₂ as the driving gas. Clauss⁵ has used one-quarter inch latex drains fastened to small-bore, spaghetti Teflon tubing as balloons. Several balloon variations have been devised (Mr. Birtwell of the Flow Rubber Corp. and the Davol Rubber Co.), and the application of electromagnetic forces to inflate and deflate conductive elastic balloons is being explored (General Atomics Division General Dynamics Corporation, San Diego, California). The only reports concerning the device which incorporates the features described herein and which was used in normal dogs as well as dogs in which cardiogenic shock was experimentally induced, have come from this laboratory.

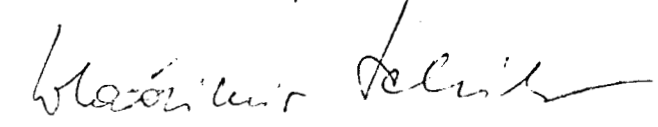
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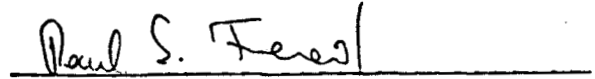
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2. Clauss et al. J. Thor. Cardio. Surg. 41:447, 1961.

3. Soroff, H.S. et al. Circulation 27:722, 1963.
4. Mouloupoulos, S.D., S. Topaz and W.J. Kolff, Am. Heart J. 63:669, 1962.
5. Clauss, R.H. in Mechanical Devices to Assist the Failing Heart, National Academy of Sciences-National Research Council, Washington, D.C., 1966, p. 251.

May 18, 1967


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